RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL P. LATTA

Appeal 2007-2397
Application 10/823,263
Technology Center 1600

Oral Hearing Held: Wednesday, September 12, 2007

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ, Administrative Patent Judges

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Wednesday, September 12, 2007, commencing at 2:27 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A, Alexandria, Virginia, before Jan M. Jablonsky, Notary Public.

JUDGE GRIMES: Whenever you're ready.

MR. ALTMAN: So, the second case is directed to what you pointed out is that an initial tolerizing dose is administered followed by a curative dose. In this case, the rejections have to do with obviousness, and the rejections are a combination. It's an alternative rejection.

There are three U.S. patents cited as primary references and each of those references is combined with a Posselt reference. There was some confusion regarding which of these Posselt references was the reference cited by the Examiner. It wasn't explicitly addressed by the Examiner, but I think it's fairly clear that it's the 1991, not the 1992 paper which was the case which was actually referred to by the Examiner.

JUDGE LEBOVITZ: And that's the *Journal* article that's actually mentioned on page 2 of the specification.

MR. ALTMAN: That's the same one, yes. Of course, and the second one is actually a follow-on to the first, but gets into some specific areas, and because of that it's really less relevant.

The three U.S. patents that were cited as primary references, each of those teaches a curative dose of islet cells used as a treatment for diabetes and addresses the issue of preventing transplant in different ways. One of them has using an immunosuppressive drug. One of them builds it around the special device, and they have various techniques for addressing

this problem which has been the problem all along in terms of addressing the issue of islet transplantation as a treatment for diabetes.

What this invention relates to is a way of tolerizing the immune system to the subsequent implantation of a curative dose. And it's analogous to the treatments that are done for allergies. An allergy medication B or allergy shots that are typically referred to, the patient goes and receives very minute doses of an allergen, and eventually the patient ends up with a tolerance to that particular allergen. It's that type of process which was exploited by the inventor in this case.

JUDGE LEBOVITZ: As you remember, was there any prior art submitted, I guess by you, that described tolerization in the context of graft host disease in the context of transplanting tissue into an organism. Certainly, there's nothing that we see in the rejection with pancreas.

MR. ALTMAN: Any other argument? I don't recall any prior art like that. I don't recall having seen any prior art like that.

JUDGE LEBOVITZ: Okay.

MR. ALTMAN: So the Examiner cited the Posselt reference for the idea that you can tolerize against islet cells. And the Posselt reference, the title itself refers to intrathymic injections for tolerance. And the difference between what Posselt is doing and what the inventor is doing is that the Posselt reference recognizes that there's something special about the thymus. And the mechanism that Posselt and his co-authors refer to is that the tolerization occurs as a direct influence on the maturing thymocytes. So this is something which is unique to the thymus.

And Posselt uses a fully curative dose, that when you go into the dose and determine how much was used, it's the same amount of dose

that could be used to treat diabetes. And this amount of islet is implanted into the thymus, because they believe the thymus was this immunologically special space and that the islet cells in the thymus continue to grow without being intact.

So while it is true that Posselt was able to achieve tolerance by injecting the islet directly into the thymus, he wasn't achieving tolerance for the subsequent implantation. In fact, when you look at Posselt, it has a section where it talks about why thymus is an immunologically special place, and one of the hallmarks of that is if the animal had been previously immunized against the same antigen, then that immuno-tolerance goes away. And he was using that to show that it was an immunologically protected and special place, because that's characteristic of these types of places that if it's a novel exposure that there is protection, but not if it's not a novel exposure.

And the present invention is entirely different because the idea is that we're going to do more than one step. We're going to have a first initial tolerizing step followed by a curative step. And so the entire idea is that we're going to create a tolerance, and then we're able to inject islets.

Now, Posselt also B just to show that thymus was really something special B he also injected islets to other sites in the body. And in these other sites, virtually all of the islets were destroyed in very short order. But he did have two rats that were able to keep the islets intact without destroying them. But in neither of these rats did any tolerization take place. So the entire conclusion of the Posselt reference is that thymus is a special place.

And so there's no suggestion at all that introduction of islets into any other part of the body could result in tolerization. And the

Examiner seems to have spent a lot of time in his answer talking about how, well, it's not really teaching a way. And, you know, maybe it's teaching. That's kind of a strong word. But I think that the bottom line is that it doesn't have any suggestion to go to anywhere other than the thymus. The Examiner had sort of a strange argument where he said, well, you use the word "comprising" and therefore you don't exclude introduction into the thymus. Well, that may be true, but we do specifically require implantation into a different site other than the thymus.

JUDGE LEBOVITZ: But in fact on '367, column 1, which is the so-called teaching away, when you give an initial dose not into the thymus and then followed by a curative dose, you actually get rejection. So you don't get tolerization under his regime.

MR. ALTMAN: That's correct. Yes.

JUDGE LEBOVITZ: But is his regime any different than the claimed regime?

MR. ALTMAN: Yes.

JUDGE LEBOVITZ: How does it differ? In '367, column 1, how does the claimed regime differ than this regime which did not work?

MR. ALTMAN: Well, there's a couple of different reasons. One, I can go down to the dependent claims where it says that the dose is a subclinical dose by one to two orders of magnitude, and those were claims 3 and 11, I believe. So those claims are clearly different because the dose that Posselt is using is a fully clinical dose.

And the other difference is that the claim -- let me find the claim, just a second -- the claim specifically says that it's a method of treating diabetes in a mammal in need thereof. And Posselt, if you followed

those steps, you would not be able to conduct a method of treating diabetes. And in fact he specifically says that the subsequent administration of the therapeutic dose is rejected.

JUDGE GRIMES: So you would interpret this claim to require effective treatment of diabetes, not just a method of trying to treat diabetes.

MR. ALTMAN: Because it does say a method of treating diabetes and it's an animal in need of such treatment. Or as an animal in need of such treatment you would not want to give Posselt's treatment. Posselt, of course, uses unencapsulated islets in the initial step and so that's the other difference between claim 1. That's what makes it into an effective treatment is the encapsulation of the first tolerizing step.

So I think that as far as this goes, the most important case that I want to make is that there's no suggestion to carry out the claim in any of the references that were cited of having a first encapsulated dose followed by a second fully curative dose. And for those dependent claims there's still another limitation which is not suggested by the references.

So that's all I have prepared for that case.

JUDGE GRIMES: I think that's all we need then.

MR. ALTMAN: Okay, thank you very much.

(Whereupon, at 2:39 p.m., the hearing was concluded.)